UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/829,201	04/22/2004	Daniel J. Drucker	016777-0616	5544

30678 7590 01/09/2008
CONNOLLY BOVE LODGE & HUTZ LLP
1875 EYE STREET, N.W.
SUITE 1100
WASHINGTON, DC 20036

EXAMINER	
JIANG, DONG	

ART UNIT	PAPER NUMBER
1646	

MAIL DATE	DELIVERY MODE
01/09/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/829,201	DRUCKER ET AL.	
	Examiner	Art Unit	
	Dong Jiang	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 October 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3 and 5-11* is/are pending in the application.

4a) Of the above claim(s) *7-11* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,5 and 6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1, 3 and 5-11* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED OFFICE ACTION

Applicant's amendment filed on 10 October 2007 is acknowledged and entered. Following the amendment, claims 2 and 4 are canceled, and claims 1, 3 and 5-8 are amended.

Currently, claims 1, 3 and 5-11 are pending, and claims 1, 3, 5 and 6 are under consideration.

Withdrawal of Objections and Rejections:

All objections and rejections of claims 2 and 4 are moot as the applicant has canceled the claims.

The rejection of claims 1, 3 and 5 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn in view of applicant's amendment and argument.

Rejections under 35 U.S.C. §112:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 6 remains rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The newly amended claim 6 is indefinite for the recitation "*treating the onset* of said medical condition" because it is unclear what it is meant. "Treating said medical condition" is suggested.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3, 5 and 6 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited in scope to a pharmaceutical composition comprising a GLP-2 receptor agonist and a GLP-1 receptor antagonist, and a kit thereof, for the use of reducing or inhibiting food intake or suppressing appetite in mice, does not reasonably provide enablement for claims to a pharmaceutical combination comprising any GLP-2 activity enhancer and any GLP-1 activity inhibitor, useful *to treat a medical condition for which treatment with GLP-2 is indicated,* (claim 1, for example). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with the claims, for the reasons of record set forth in the last Office Action mailed on 10 April 2007, at pages 4-6.

Applicants argument filed on 10 October 2007 has been fully considered, but is not deemed persuasive for the reasons below.

At pages 6-7 of the response, the applicant argues that the MPEP is clear in its explanations that "[c]ompliance with the enablement requirement of 35 U.S.C. §112, first paragraph, does not turn on whether an example is disclosed", and "[t]he presence of only one working example should never be the sole reason for rejecting claims as being broader than the enabling disclosure." *Id.* Applicants further argue, at page 7 of the response, that applicants provide teachings as to how methods and combination according to the present invention may be adapted for use in different species. This argument is not persuasive because, while the examiner acknowledges that working examples are not required in order to be in compliance with the enablement requirement of 35 U.S.C. §112, first paragraph, the rejection is made based on the standard analysis of multiple factors ("Wands factors") with respect to enablement. For example, as addressed in the last Office Action, the breadth of the claims is very broad, which embraces a broad class of diseases or disorders, and a broad class of genus of subjects being treated, yet the specification merely discloses one particular condition that may be treated with the claimed method in a mouse model. As addressed in the last Office Action, the unpredictability in this field is indicated in the prior art, which is evidenced by Tang-Christensen et al. (Nature Medicine, 2000, 6(7): 802-807) using a rat model, wherein the GLP-1 receptor antagonist, exendin(9-39), when used with GLP-2 centrally, has completely different effects on

GLP-2-induced anorexia in mice and rats. Further, with respect to the argument that methods and combination according to the present invention may be adapted for use in different species, it is not persuasive because of the existence of the opposing evidence. Additionally, intracerebroventricular administration of drugs for inhibiting food intake (as demonstrated in the present specification) would not be a practical treatment method in humans, and the specification has not shown any other way of administration that would be as effective. Furthermore, the issue is beyond "adapted species", as the claims encompass a broad class of diseases or disorders, which are not predictable as to whether the presently claimed combination would be effective in treating all disorders or diseases for which "treatment with GLP-2 is indicated". Clearly, undue experimentation would be required of the skilled artisan to determine what conditions/diseases encompassed by the claims can be treated with the claimed pharmaceutical composition prior to use the claimed invention in its full scope.

Claims 1, 3, 5 and 6 remain further rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record set forth in the last Office Action mailed on 10 April 2007, at pages 8-9.

The amended claim 1 recites a pharmaceutical combination comprising "a GLP-2 receptor *agonist* and a GLP-1 receptor *antagonist*", which, like the previously used terms "enhancer" and "inhibitor", read on any or all functional equivalents thereof, as no structural limitation is required. Thus, the claims are drawn to a genus of molecules, which is defined only by functional limitation, and thus, encompasses extreme structural dissimilarity. For example, they can include antibodies, peptides, small chemical molecules. However, the specification discloses merely *one* a GLP-2 receptor agonist Gly^2GLP-2; and *one* GLP-1 receptor antagonist, exendin(9-39), and no other GLP-2 receptor agonist, or GLP-1 receptor antagonist meeting the limitations of the claim is identified or particularly described.

Therefore, as addressed in the last Office Action, only the GLP-2 receptor agonist Gly2GLP-2, and the GLP-1 receptor antagonist exendin(9-39) meet the written description

provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Conclusion:

No claim is allowed.

Advisory Information:

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 571-272-0872. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Lorraine Spector

LORRAINE SPECTOR
PRIMARY EXAMINER

Dong Jiang, Ph.D.
Patent Examiner
AU1646
12/12/07